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F1U UA U6

(56) Documents cited
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(58) Field of search
UK CL (Edition K) B1X
INT CL[5] A61M, B01D

(54) Fluid control apparatus

(57) A fluid control apparatus, particularly for controlling the quantity of fluid and/or solutes removed from or input into a patient during kidney dialysis, which is connected at/or adjacent to a treatment membrane in order to predictably control the flow of fluid across it.

In use, blood is pumped in lines 51, 56 and fluid is circulated by pumps 60, 65 to and from the dialyser. In this arrangement, no net flow of fluid passes from the blood side of the dialyser 53 to the other side. A net flow of fluid across the filtration membrane may be achieved by pumping fluid to vessel 73 using pump 71. In this case, fluid flows across the dialyser 53 from the patient in dependence upon the volume of fluid removed by pump 71. Thus, volumetric control of fluid removed from the patient may be achieved.

The apparatus may be of general use in filtration or for dialysis treatment. The apparatus may be modified so that haemofiltration may be effected.

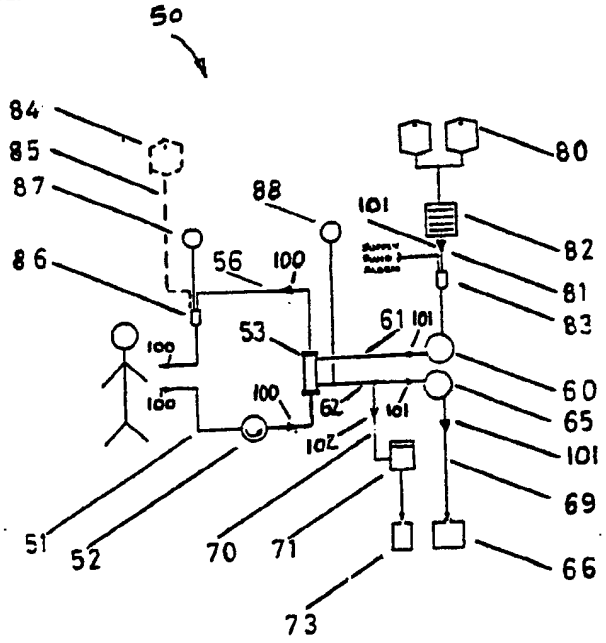

FIG.3

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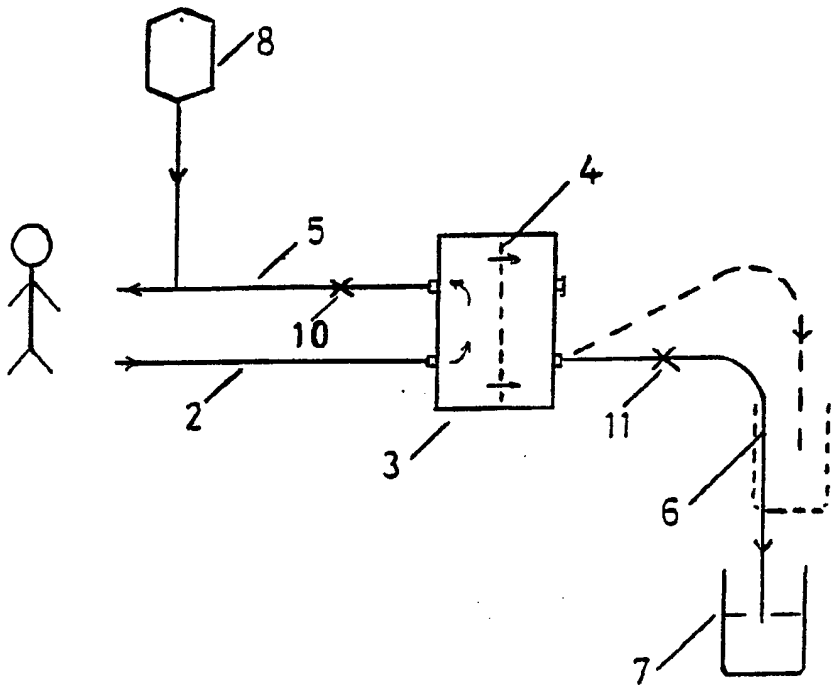

FIG. 1

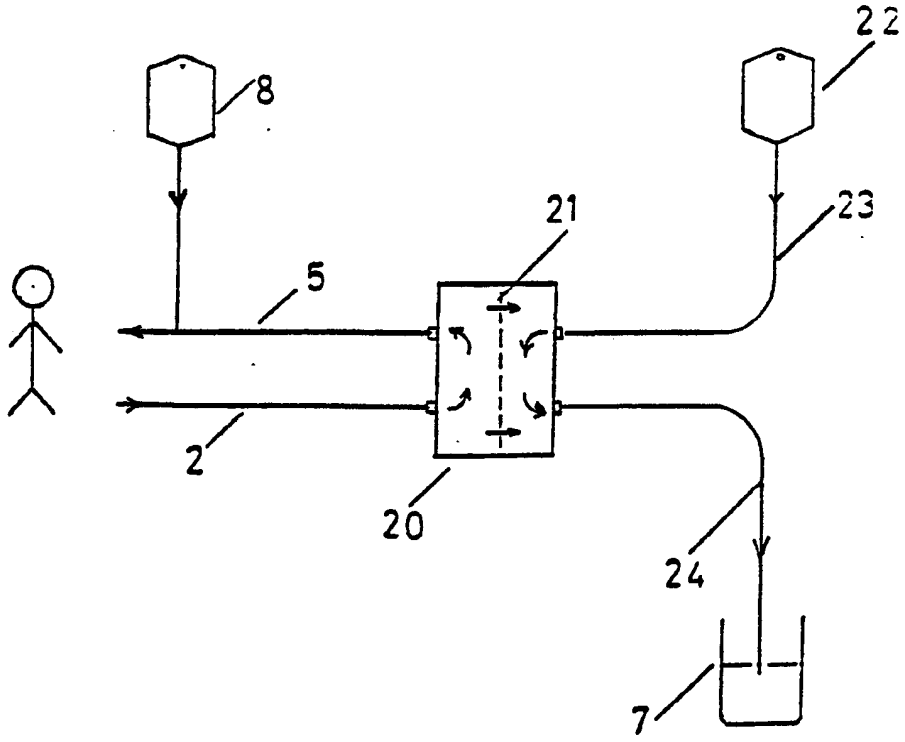

FIG. 2

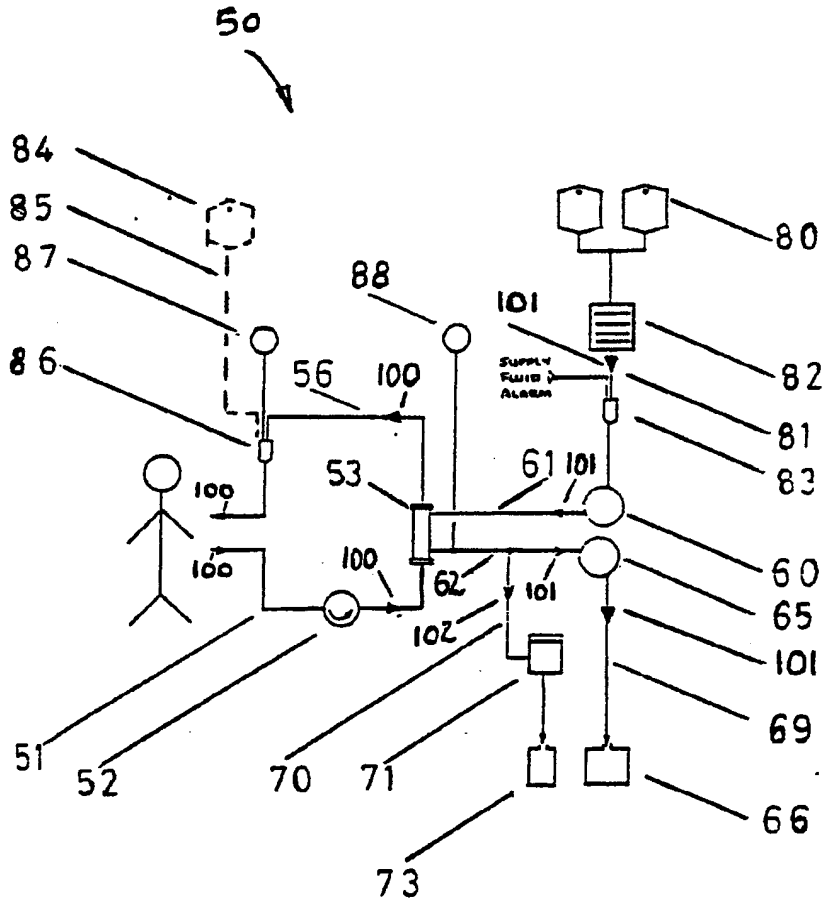
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FIG.3

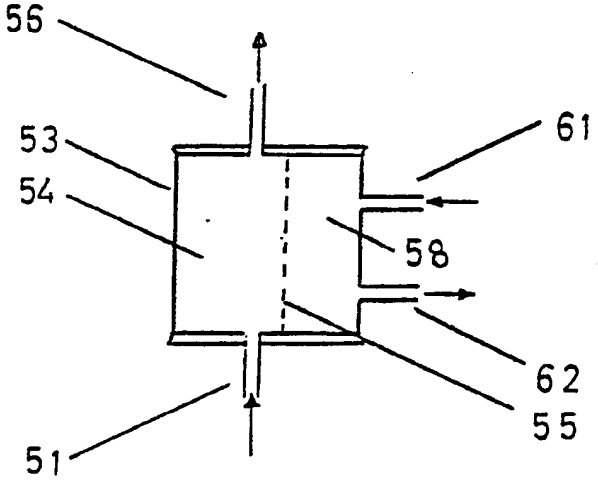
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FIG.4

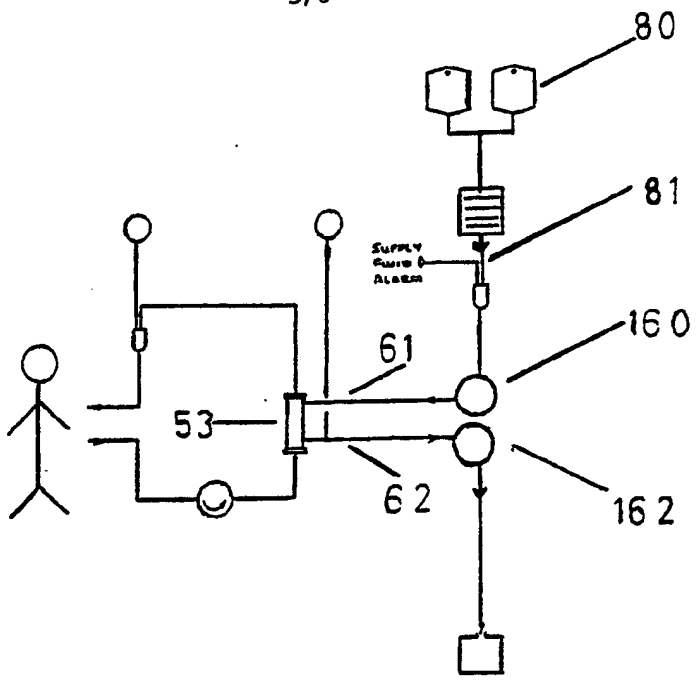

FIG. 5

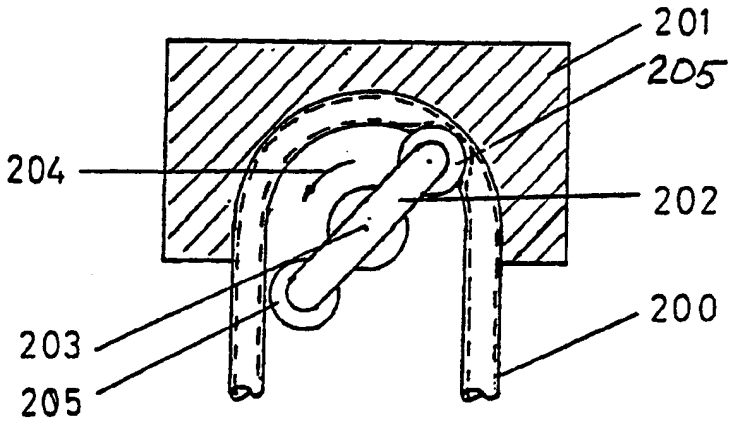

FIG. 6

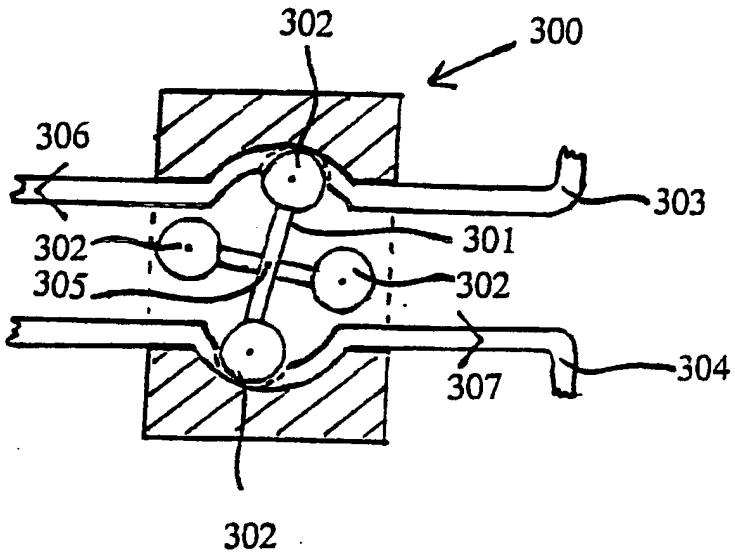
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FIG. 7

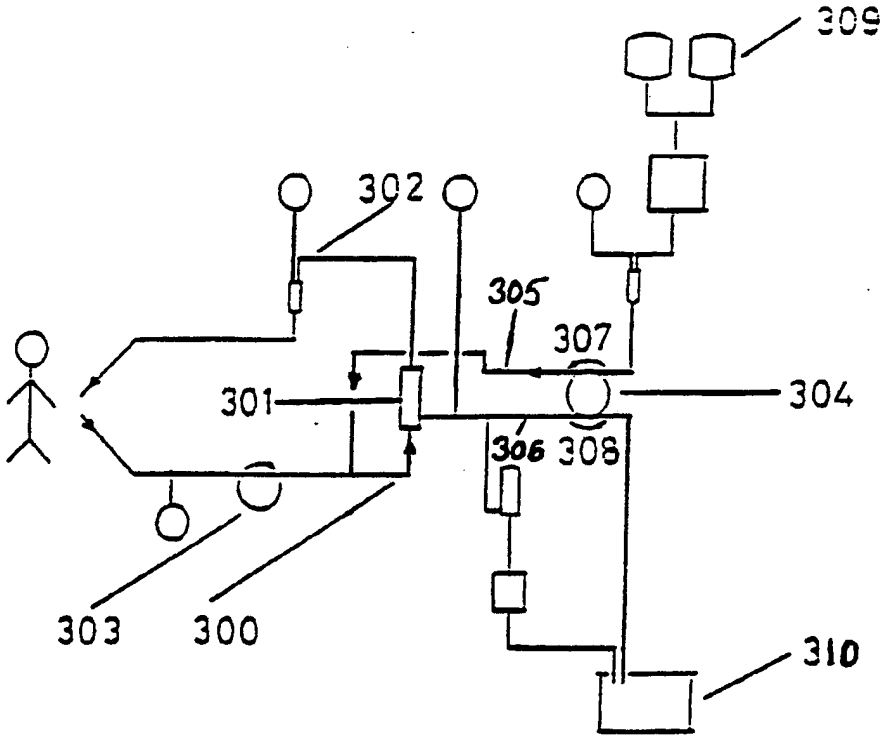
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FIG. 8

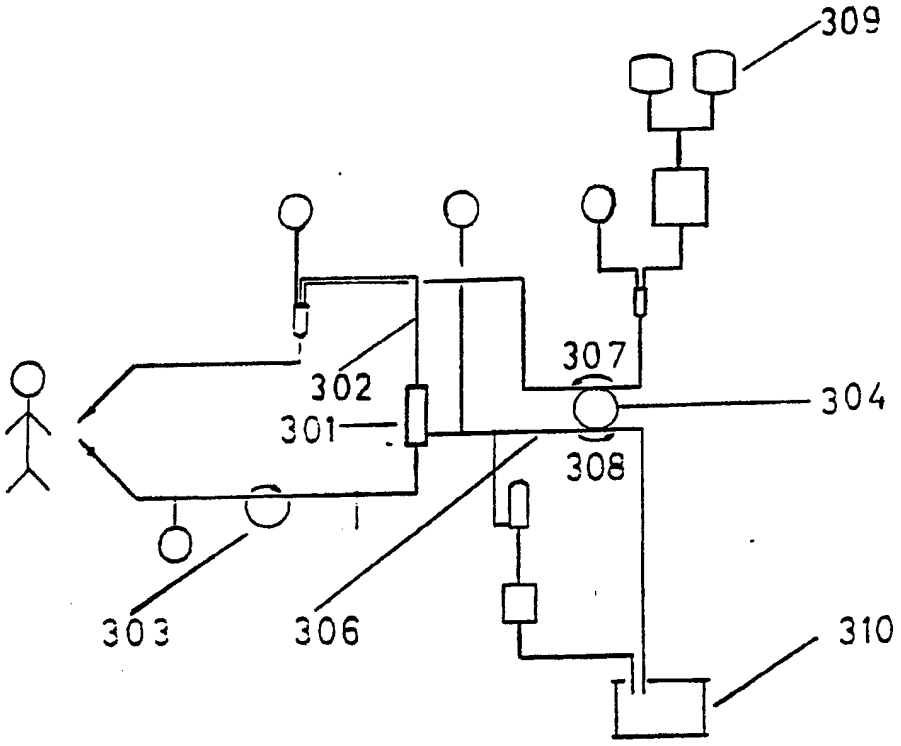

FIG. 9

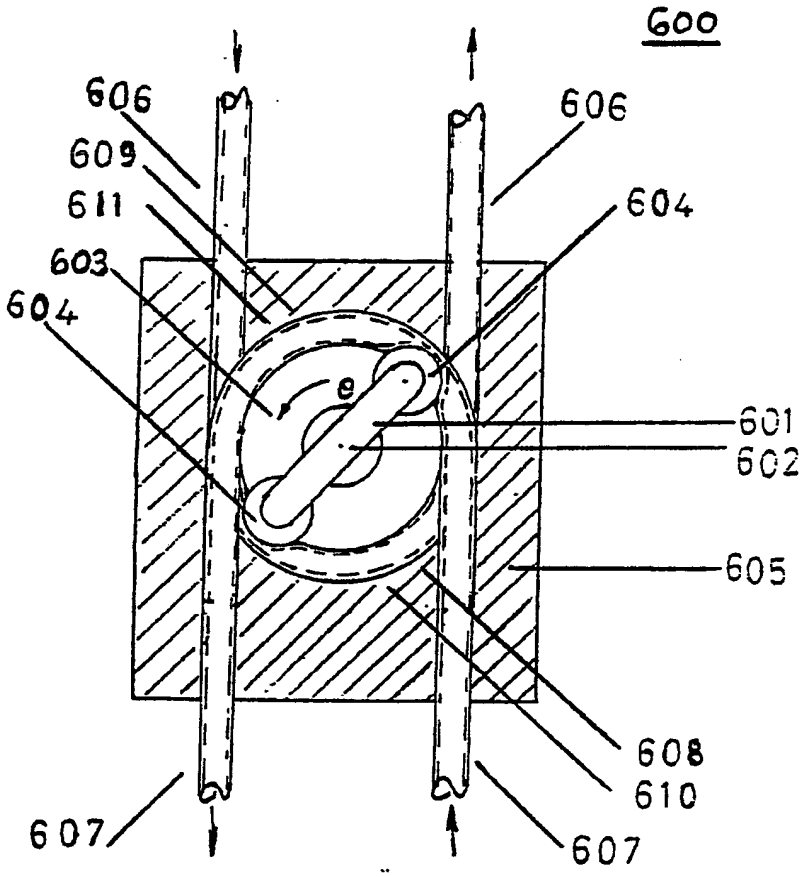

FIG.10

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FLUID CONTROL APPARATUS

This invention relates to fluid control apparatus and particularly, although not exclusively, provides apparatus for controlling the quantity of fluid and/or solutes removed from or input into a patient.

The human kidney is an essential homeostatic organ. It is involved in excretion of unwanted metabolic products and the regulation of the water content of the blood. Kidney failure may arise from trauma, infection or major surgery and this failure is a commonly encountered problem in a hospital's intensive care unit, carrying a high mortality rate.

It is known to provide artificial kidney machines which are linked into, and become a part of, a patient's blood transport system, so as to take over the task of eliminating waste products and water from a patient in the place of the patient's damaged kidney. Figure 1 of the accompanying drawings is a diagrammatic representation of a known continuous arteriovenous haemofiltration apparatus.

One end of a blood input tube 2 is linked to an artery of a patient. The other end of the tube 2 is attached to an upstream side of a filter 3 having a filtration membrane 4. A blood output tube 5 leads from the filter 3 back into a vein of the patient. A filtrate output tube 6 is attached to the filter 3 on the downstream side of the filtration membrane 4.

In use, blood is pumped by the patient's own arterial blood pressure down input tube 2 to the filter, whereupon some blood is filtered. Some blood then flows down output tube 5 back to the patient. Filtrate passes through the filtration membrane 4, out of th filter 3, via ouput tube 6 where it is collected in a container 7. Infusate 8 may

be directed into output tube 5 for replacing and/or replenishing the patient's body fluids.

The quantity of fluid removed using this apparatus will depend on a number of factors; for example, the patient's arterial blood pressure; the diameter of tubes 2, 5 and 6; and the permeability of the filtration membrane 4. Additionally, the viscosity of the patient's blood will affect filtrate quantity and, in particular, if the blood starts to clot (as it is prone to do), the pressure on the upstream side of the filtration membrane 4 will increase, leading to an unpredictable effect on the amount of fluid removed. All of the above mentioned factors are largely unmeasurable and, therefore, the exact control of the quantity of fluid removed by the apparatus is impossible. The inadequacies of the apparatus are furthermore highlighted by noting that attempts to control fluid removal include the use of adjustable clamps, for example, at positions 10, 11 which constrict either one of respective tubes 5, 6 so as to adjust the pressure gradient across the filtration membrane 4 and control the flow of fluid into container 7. Furthermore, flow rate may be decreased by raising the level of tube 6 (as seen in dotted lines in Figure 1) effectively increasing hydrostatic pressure on the downstream side of the filtration membrane 4, or flow rate may be increased by lowering the level of tube 6 to decrease hydrostatic pressure on the downstream side.

It will be appreciated from the above that accurate control of the volume of fluid removed or the rate of fluid removal is <u>not</u> possible.

A further known apparatus is shown in Figure 2 of the accompanying drawings which figure is a diagrammatic

representation of a continuous arteriovenous haemodialysis apparatus. In the figure, the filter 3 of Figure 1 is replaced by a dialyser 20. Blood flows via tubes 2 and 5 on one side of a dialyser membrane 21. On the other side of the dialyser membrane 21, dialysate fluid flows from a supply 22 via dialysate input tube 23 and dialysate output tube 24 to a container 7.

The control of the amount of fluid removed from the patient is as problematic as stated in relation to the Figure 1 embodiment, and accordingly, accurate control is impossible.

In general terms, patients with multi-organ failure often have a great deal of circulatory instability. Though continuous arteriovenous haemofiltration and continuous haemodialysis are, at present, playing an important role in the management of patients in intensive care units, the following problems may be associated with such techniques:

(i) Even with inotropic support, the patient's blood pressure may be too low to provide an effective ultrafiltration or dialysis rate;

(ii) The removal of volume from the arterial side of the circulation may exacerbate circulatory instability;

(iii) As control of the ultrafiltration rate or dialysis rate is often achieved by a gate clip on the filter or dialyser output line, considerable experience and care is required if the desired fluid removal is to be achieved smoothly and with minimum trauma to the patient; and

(iv) Prolonged arterial catheterisation may be accompanied by haemorrhage, false aneurysm formation and limb ischaemia.

We aim to improve upon the aforementioned by providing apparatus which may alleviate at least some of the problems associated with known apparatus and techniques.

According to one aspect of the invention, there is provided, apparatus for treating a patient, a part of which apparatus is arranged to be connected, in use, at or adjacent a treatment membrane having a first side and second side so that body fluid may flow to the first side of the membrane, the apparatus comprising control means for controlling predictably the flow of the fluid across the treatment membrane.

Thus, the apparatus may be used in haemodialysis wherein there is no net gain or loss of fluid to or from the patient or in haemofiltration.

Preferably, said control means includes means for controlling predictably the volume of fluid flowing across the treatment membrane. Preferably, said control means is arranged to control predictably the net volume of fluid flowing across the treatment membrane. Preferably, said control means includes means for controlling predictably the rate of flow of fluid across the treatment membrane. Preferably said control means is arranged to control the net rate of flow of fluid across the treatment membrane.

The apparatus may include an occluded fluid flow line having an occlusive pump means at each end thereof, the

fluid flow line being arranged to deliver fluid to the treatment membrane and to remove fluid therefrom.

The apparatus may include an occluded fluid flow line having an occlusive pump means at each end thereof so as to define a fluid path which is disposed on each side of the treatment membrane. The fluid path may pass from one side of the membrane to the other.

Occlusive pumps per se may be used exclusively to control some or all fluid flow conditions, for example, to control exclusively the volume of fluid flowing in a particular fluid flow path and/or to control exclusively the rate of flow of fluid in a particular fluid flow path.

Preferably, means for measuring the quantity of fluid flowing across the treatment membrane is provided.

Preferably, first pump means is provided for delivering a fluid to the second side of the membrane and second pump means is provided for removing fluid from said second side.

Alternatively, in haemofiltration, said first pump means may be arranged to deliver a fluid to a position on the first side of the treatment membrane, for example, into a fluid flow path which is arranged to deliver fluid to the first side of the treatment membrane (pre-dilutional haemofiltration) or into a fluid flow path from the first side of the treatment membrane (post-dilutional haemofiltration). In haemofiltration, the second pump means may be arranged to remove fluid from the second side of the treatment membrane.

Preferably, a fluid flow path between the first and second pump means is totally occluded. To this end, preferably, said first pump means is an occlusive pump, for example, a peristaltic pump. Said second pump means is also preferably an occlusive, for example, a peristaltic pump. Preferably, a link means is provided between said first and second pump means for controlling the relative rates of the respective pumps. Said link means may be, for example, mechanical or electrical.

Preferably, said pump means is arranged to pump fluid in a predetermined fashion. Preferably, said first and second pump means are arranged to pump fluid at the same rate. Said first pump means may co-operate with a first fluid supply pipe provided between said first pump means and the treatment membrane and said second pump means may co-operate with a second fluid supply pipe provided between said second pump means and the treatment membrane, said first and second fluid supply pipes being of equal cross-sectional area. Alternatively, said first pump means may co-operate with a first fluid supply pipe provided between said first pump means and the treatment membrane and said second pump means may co-operate with a second fluid supply pipe provided between said second pump means and the treatment membrane, said first and second fluid supply pipes being of different cross-sectional areas.

Preferably, the control means is arranged to deliver fluid to the second side of the treatment membrane and arranged to remove fluid from the second side of the treatment membrane, wherein the rate at which fluid is delivered to the membrane is substantially equivalent to the rate at which fluid is removed from the membrane. Preferably, the control means is arranged to produce a

fluid disequilibrium on one side of the treatment membrane and the arrangement being such that fluid is caused to flow across the membrane so as to re-equilibriate. Said fluid disequilibrium may occur between said first and second fluid supply pipes. Preferably, in use, fluid flows between the patient connected on the first side of the treatment membrane and the second part of the treatment membrane in order to re-equilibriate. Preferably, the arrangement of the apparatus is such that fluid removal or fluid input into said fluid flow path between said first and second pump means is arranged to cause body fluid to flow respectively from the first side of the treatment membrane to the second side, or from the second side of the treatment membrane to the first side.

Preferably, a third pump means is provided in said flow path between said first and second pump means. Said third pump means is preferably arranged to remove or input fluid into said fluid flow path between the first and second pump means and control the volume and/or rate of flow of fluid flowing between the first side and the second side of the treatment membrane. Said third pump means is preferably an occlusive pump, for example, a metering (or volumetric peristaltic) pump.

Preferably, a fourth pump means is provided and arranged to be connected in a fourth fluid supply path between the patient and the first side of the treatment membrane. Preferably, said fourth pump means is an occlusive pump, for example, a peristaltic pump.

In pre-dilutional or post-dilutional haemofiltration, the control means may be arranged to deliver fluid to the first side of the treatment membrane so as to pre-dilute or post-dilute the patients blood and the control means

may be arranged to remove fluid from the second side of the treatment membrane.

The apparatus may include a catheter, for example, a venous catheter, attached and arranged to co-operate with the fourth fluid supply path.

Said treatment membrane may be a dialysis membrane, or a filtration membrane. The apparatus may include a treatment membrane, such as a dialysis membrane, or a filtration membrane. The apparatus may include a dialysate supply means arranged to deliver dialysate into said fluid flow path and/or alarm means for indicating when said dialysate supply needs replenishing and/or infusate supply means which may be arranged to input infusate into said fourth fluid supply path. The apparatus may include infusate control means for controlling and monitoring the supply of infusate into said fourth fluid supply path.

The invention extends to a fluid pump comprising a plurality of abutment means rotatably mounted for rotation about an axis, and comprising one or a plurality of abutment surface(s) arranged to cooperate with the abutment means so that, in use, a pipe may be squeezed between an abutment means and an abutment surface, the pump being arranged to pump fluid through at least two pipes, the arrangement being such that, at one instance in use, one pipe may be squeezed at a first location and another pipe may be squeezed at a second location, the first and second locations being substantially radially disposed of said axis with an angle Θ defined between the radii, wherein Θ is greater than 0 .

Preferably, Θ is 180°. That is, the first and second locations are substantially diametrically opposed. Two or four abutment means may be provided. The abutment means may be mounted on radial arms pivotable about said axis.

Said fluid pump may be provided in combination with the invention according to any aspect.

The invention extends to a method of kidney dialysis or kidney or liver filtration comprising connecting the aforementioned apparatus to a patient and operating the apparatus so as to dialyse or filter the patient's blood.

By way of example, specific embodiments of the invention will be described, with reference to the accompanying diagrammatic drawings in which:-

Figure 3 is a diagrammatic representation of haemodialysis apparatus.

Figure 4 is a diagrammatic representation of a dialyser.

Figure 5 is a diagrammatic representation of an alternative haemodialysis apparatus;

Figures 6 is a diagrammatic representation of an occlusive peristaltic pump;

Figure 7 is a diagrammatic representation of an alternative occlusive peristaltic pump;

Figures 8 and 9 are diagrammatic representations of pre-dilutional and post-dilutional haemofiltration apparatus respectively; and

Figure 10 is a representation of a pump.

In Figure 3, the haemodialysis apparatus 50 comprises a blood delivery line 51 having a first occlusive peristaltic pump 52 arranged to drive fluid through the line 51 towards a dialyser 53.

The line 51 leads into one part 54 of the dialyser 53 (Figure 4), namely the blood part of the dialyser. The blood part 54 is separated from a dialysate part 58 by a semi-permeable membrane 55. A blood return line 56 is attached to the blood part 54 of the dialyser.

A second occlusive peristaltic pump 60 is arranged to drive fluid through a dialysate delivery line 61 to the dialyser 53. The dialysate delivery line 61 communicates with the dialysate part 58 of the dialyser 53 (Figure 4). A dialysate return line 62 is attached to the dialyser part 58. A third occlusive peristaltic pump 65 is arranged to drive fluid from the dialysate part 58 along the return line 62 and then along a fluid line 69 towards a waste vessel 66.

A fluid line 70 communicates with the return line 62, between the dialysate part 58 and the third pump 65. A fourth occlusive metering pump 71 is arranged to drive fluid along the fluid line 70. The fluid line 70 leads into a container 73.

As indicated, pumps 60 and 65 are occlusive peristaltic pumps. An occlusive peristaltic pump does not

contact the fluid being pumped. It effectively squeezes the tube, for example, dialysate delivery line 61 or return line 62, to push fluid through the tube. A simplified diagrammatic representation of an occlusive peristaltic pump is shown in Figure 6 wherein a length of resilient plastic tube 200 is held in position by suitable means (not shown) against a rigid back member 201. A pump arm 202 is pivotally mounted at pivot point 203, the arm being arranged to rotate about point 203, in the direction shown by arrow 204, by a suitable means, for example, an electric motor. The arm 202 carries, at each end, a rotable rigid abutment member 205.

The arrangement of the apparatus is such that, in use, the abutment member 205 may totally occlude the tube 200, the tube 200 being squeezed between the abutment member 205 and the back member 201. As the arm 202 rotates in an anticlockwise direction, fluid present in tube 200 is pushed in front of the point of contact of the abutment member 205 with the tube 200 and, therefore, driven through the tube 200. Each of the abutment members 205 may squeeze the tube at one time. At another time (seen in Figure 6) during rotation of the arm 202 one of the abutment members 205 will not be suitably disposed to occlude the tube 200. Nevertheless, it should be noted that at all times during rotation of the arm 202, at least one of the respective abutment members 205 totally occludes the tube 200.

The haemodialysis apparatus 50 also includes a dialysate supply 80 communicating via a fluid line 81 with dialysate delivery line 61, the pump 60 being arranged to drive fluid from the supply 80 to the delivery line 61. In the fluid line 81, there is provided a heating device 82 and a supply fluid alarm means 83.

An infusate supply 84 communicates via a fluid line 85 and a valve 86 with blood return line 56. First pressure monitoring means 87 and second pressure monitoring means 88 are arranged to measure pressure in blood return line 56 and dialysate return line 62 respectively. An anticoagulant, for example, heparin or prostacyclin, supply means (not shown) is provided and arranged to feed anticoagulant into line 51.

The apparatus may be used as follows, for example, in venovenous haemodialysis. A dual lumen venous catheter is inserted in a major vein, for example, the internal jugular or subclavian vein of a patient. One lumen of the catheter is arranged to communicate with blood delivery line 51, the other lumen being arranged to communicate with blood return line 56 so as to provide a continuous passage from the vein to the respective lines 51, 56. The first pump 52 may then be operated to pump blood through blood delivery line 51, through the blood part 54 of the dialyser 53, through the blood return line 56 and back to the patient in a closed system, as indicated by arrows 100.

With dialysate fluid in the supply 80, the second pump 60 and the third pump 65 are switched on. Fluid therefore flows from supply 80, through fluid line 81, through dialysate delivery line 61, through the dialysate part 58 of the dialyser 53, through the dialysate return line 62, through fluid line 69 to the waste vessel 66, as indicated by arrows 101.

It should be noted that the second pump 60 drives dialysate fluid to the dialyser 53 and the third pump 65 drives fluid from the dialyser 53. The second pump 60 and the third pump 65 are mechanically linked by a suitable

linking means (not shown), so that, when in use, their respective pumping actions are synchronised.

Given that the diameter of delivery line 61 and the diameter of dialysate return line 62 have substantially exactly the same cross-sectional area, and with the second pump 60 and third pump 65 being synchronised and working at identical rates, the rate of flow of fluid into the dialyser 53 equals the rate of flow of fluid from the dialyser. Thus, a constant flow of dialysate passes through the dialysate input line 61, through the dialysate part 58 of the dialyser, through the dialysate return line 62 and through the fluid line 69 to the waste vessel 66. Thus, there is no net gain or loss of fluid from the blood part 54 of the dialyser 53 to the dialysate part 58. Nevertheless, it should be noted that osmosis will take place across the semi-permeable membrane 55 and, accordingly, the blood will be "cleaned". It is preferable, in certain situations, depending on the type of treatment membrane used, to use sterile dialysate in supply 80 to minimise the risk of patient infection during osmosis.

The rate of osmosis may be controlled, to some extent, by controlling the rate at which pumps 60 and 65 pump dialysate to the membrane 55, as the rate of pumping will affect the concentration gradient across the semi-permeable membrane 55.

The use of the apparatus 50 as described above to "clean" the blood whilst accurately maintaining patient blood volume may substantially reduce patient trauma.

When it is required to remove a measured amount of fluid from the patient, the fourth pump 71 is actuated.

The pump 71 withdraws fluid from line 62 as indicated by arrow 102. This fluid removal causes fluid pressure in line 62 to fall and accordingly, the equilibrium of the system will become unstabilized. However, as pumps 60 and 65 totally occlude respective lines 61, 62 so that fluid can only flow when driven by the respective pumps 60 and 65 and as the pumps 60 and 65 are synchronised so as to pump fluid at the same rate, a new stable fluid equilibrium cannot be achieved by input of additional fluid into the dialysate lines 61, 62 from the supply 80. The only source of fluid available to input into fluid line 62 and restore equilibrium is from the blood part 54 of the dialyser. Thus, equilibrium is restored due to a net volume of fluid flowing from the patient through line 51 and across the membrane 55. (The membrane 55 is selective in that in general only unwanted products pass through in the fluid, such as water and toxins; blood cells, hormones etc. will not in general be removed).

It should be noted that the quantity of dialysate captured in container 73 is substantially volumetrically exactly the same (within accepted tolerances of the apparatus etc.) as the amount of fluid removed from the patient. This is due to the equality of flow rates into and out of the dialyser due to the synchronicity of pumps 60, 65 and the fact that the only source of fluid to restore the equilibrium is from the patient side of the dialyser 53.

A measured amount of fluid may be inputted into the patient from supply 84, as required. This may be carried out manually, for example, by means of an operator controlling a gate clamp. Preferably, a computer controlled valve is used. It should be appreciated that the amount of fluid infused into the patient may be based

upon the amount removed and captured in container 73 and the rate at which, and amount of, fluid removed from the patient may be balanced to the rate at which, and amount of, fluid infused back into the patient, as required. This may serve to substantially reduce patient trauma.

It should now be appreciated, that the rate at which pump 71 drives fluid along line 70 generally equals the rate at which fluid passes from the blood part 54 of the dialyser to dialysate part 58 thereof and, in turn, generally equals the rate at which fluid is removed from the patient. Control means (not shown) is provided to control the speed of pump 71 and, thus, this control means effectively controls the rate of removal of fluid from the patient. Furthermore, it will be appreciated that for a known flow rate, the volume of fluid to be removed from a patient may be predetermined by varying the time for which the pump 71 is actuated, as required.

Suitably, the flow rate of fluid through lines 61, 62 may be selected in the range 30 ml/min (1.8L/hr) to 333 ml/min (20L/hr). This is less than the 500 ml/min often used in conventional machines. Suitably, the rate of removal of fluid from a patient may be selected in the range 0 to 1000 ml/hour.

Infusate, containing, for example, water, essential salts etc. may be inputted into the line 56 depending on whether valve 86 is open or closed.

Dialysate may be warmed by the heating device 82 as it passes along line 81.

The pressure in lines 56 and 62 may be monitored by means of pressure monitoring means 87 and 88 respectively.

The anticoagulant supply means may be actuated as required to deliver anticoagulant into blood input line 51.

It should be noted that the quantity of fluid removed by apparatus 50 may not, in general, be affected by uncontrollable factors, for example, the patient's arterial blood pressure, the permeability of the filtration membrane and the viscosity of the patient's blood, as in the prior art mentioned previously; that is, the quantity removed may be controlled, irrespective of pressures generated in the blood compartment by the blood flow. The amount of fluid removed depends on conditions appertaining on the dialysate side of the dialyser 53. Even if the blood starts to clot in line 51, the amount of fluid removed from the patient will not be affected, provided, of course, that there is some fluid present in the blood part of the dialyser 53 which can pass through the membrane 55 to replace dialysate removed by pump 71.

The apparatus 50 may be modified and augmented in many ways. For example, blood monitoring means may be provided to monitor concentrations of solutes (eg. sodium ions, potassium ions, lactate, urea, creatinine, alcohol, poisons etc.), the patient's blood pressure, blood viscosity and, in particular, whether the blood is in danger of clotting, in one or both of blood lines 51 and 56. The information may be continuously fed into a computer to control any action necessary to alleviate low blood sodium levels, high pH or high water levels etc. The action necessary may include inputting a predetermined amount of sodium into the patient's blood, inputting a predetermined amount of an acetate buffer into the blood or removing water from the blood by actuating the fourth pump 71 for a predetermined time so as to remove fluid

from the patient's blood. Alarm means may be provided, for example alarm 83, so as to alert when either the apparatus or the patient require human intervention, for example, when dialysate 80 needs replenishing. Further alarm means may be provided to detect, for example, if the patient's blood pressure falls to a dangerously low level.

A patient may be connected to apparatus 50 for a long period of time without the need for constant human intervention and supervision. Reduction in human intervention and supervision may provide substantial cost savings. Furthermore, dialysate may be caused to flow relatively slowly, compared to prior known apparatus, through apparatus 50 and fluid may suitably be removed from the patient much more slowly than in the prior art machines - to some extent the apparatus 53 may behave more like a human kidney. For example, in an intensive care situation, the apparatus 50 may be used to remove a desired quantity of fluid over a 44 hour period whereas in prior known machines the same quantity of fluid may be removed in only 4 hours. Alternatively, the apparatus may be used in an intensive care situation simply to "clean" the patient's blood with no net loss or gain of fluid from or to the patient. Furthermore, slow dialysis may increase the efficiency of removal of unwanted molecules. Using the apparatus 50, therefore, may reduce the amount of dialysate needed in a particular situation and thereby provide substantial cost savings. As mentioned previously, sterile dialysate may be used in supply 80 of apparatus 50. Such sterile dialysate may be circulated through the dialyser 53 a plurality of times. As this sterile dialysate will only become "contaminated" by the patient's blood during passage through the apparatus 50, there are unlikely to be any detrimental ffects on the patient should some such contaminated dialysate pass to

the blood part of the dialyser. The use of recirculated dialysate may further reduce the costs involved in a treatment. Thus, the apparatus may be used as a substantially autonomous means of monitoring and controlling fluid and solute levels in a patient's bloodstream.

Any pump that may be arranged to function in an occlusive manner may be of utility instead of the occlusive peristaltic pumps described above.

As previously mentioned, the second pump 60 and third pump 65 are mechanically linked. Such a linkage may take a number of alternative forms; for example the arm 202 of each pump may be mounted on a single driven shaft so that rotation of the shaft causes rotation of the respective arms of each of pumps 60 and 65. Alternatively, each arm of pumps 60, 65 may be mounted on separate shafts, each respective shaft being driven, via intermediate gearing, by a single driven shaft. In a further alternative arrangement, each shaft of a respective pump 60, 65 may be driven by a respective motor, the rate of the respective motors being computer controlled thereby to synchronise the pumps as desired.

A means of linking two pump means is shown in Figure 7. In the Figure, a pump 300 includes a cross-shaped pump head 301, having four abutment members 302 which are arranged so that each of fluid pipes 303, 304 are totally occluded at any one time. Rotation of the pump head 301 about an axis 305 causes fluid to be pumped along pipes 303, 304 in the direction of arrows 306, 307 respectively. This pump 300 may be a particularly advantageous way of providing linked pump means and may be of general use in any of the embodiments described herein. The pump 300

may, furthermore, be relatively durable and reliable, as it should be noted that, an equal and opposite force is applied to opposite abutment members 302 by respective pipes 303,304, and, accordingly, there is no resultant stress on axis 305, as may be the case in relation to the Figure 6 embodiment.

An additional means of linking two pump means is shown in Figure 8. In the Figure, a pump 600 includes an arm 601, pivotally mounted at pivot point 602, the arm 601 being arranged to rotate about point 602 in the direction of arrow 603 by suitable means. The arm 601 carries, at each end, a rotatable rigid abutment member 604, the abutment members being disposed at an angle Θ which is 180° in the embodiment. A stepped abutment member 605 is provided. The member 605 is arranged to receive pipes 606 and 607. In the region of respective arcs 608, 609 of the pipes 606, 607, the member 605 provides abutment surface regions 610, 611, against which respective pipes 606, 607 may be urged by abutment members 604, in use.

In use, the arm 601 rotates and the abutment members 604 co-operate with the abutment surface regions 610, 611 so as to occlude the pipes 606, 607. It should be noted that at any one time, each of pipes 606, 607, is totally occluded. It may be noted that pipes 606, 607 leave the pump 600 from the same side from which they entered the pump 60. The pipes are, therefore, led through an angle of 180° in the pump.

A number of variations and extensions of the apparatus 50 may be provided, as follows:-

The apparatus 50 may be used in reverse so as to cause fluid and/or solute to pass from the dialysate part 58 of the dialyser to the blood part 54. To do this, the fourth pump 71 may be reversed so as to pump, for example, sterile plasma from container 73 into return line 62. This will tend to increase the fluid pressure in return line 62. As discussed previously, the supply lines between pumps 60, 65 and 70 provide an occluded system so that when fluid pressure within one or more of the lines 61, 62 or 70 is increased or reduced, a new equilibrium is established due to fluid leaving or entering respectively the supply lines via the dialyser. Thus, an increase in fluid pressure in return line 62 is reduced and a new equilibrium established due to fluid flowing from the dialysate part to the blood part of the dialyser. Additionally, it will be appreciated that fluid may be inputted into line 61, subsequently causing fluid to pass to the blood part of the dialyser.

An alternative means of controlling the rate at which fluid is removed from a patient and ultimately have volumetric control of fluid removal, is shown in Figure 5. In that Figure, the apparatus is generally as shown in Figure 3, except that line 70 and pump 71 are eliminated. A second pump 160 and a third pump 161 are provided to control fluid removal from the patient. A control means (not shown) is provided for controlling the relative speed of pumps 160 and 162.

Presuming that the cross-sections of lines 61 and 62 are identical, with pumps 160 and 162 working at the same rate, the rate of flow of fluid into the dialyser 53 will equal the rate of flow of fluid from the dialyser, as discussed in relation to the Figure 3 embodiment. If for example, however, pump 160 is set to run at 50 revolutions

per minute (r.p.m.) and pump 162 is set to run at 51 r.p.m., there will be a fluid disequilibrium and so fluid will be drawn from the patient side of the dialyser through the dialysis membrane into the dialysate side of the dialyser to restore the equilibrium. Thus, fluid will be removed from the patient in dependence upon the relative speeds of pumps 160 and 162. Provided the rates of pumps 160 and 162 are precisely controlled and these rates are accurately known, the rate of removal of fluid and fluid volume removed can be predetermined.

The aforementioned embodiments may be modified so as to effect filtration instead of dialysis, so as to provide a means of volumetric haemofiltration.

A pre-dilutional haemofiltration apparatus is shown in Figure 8. The apparatus includes a blood delivery line 300 which is connected to the blood part of a filter unit 301. A blood return line 302 leaves the blood part of the filter unit 301 so as to return filtered blood to the patient. An occlusive peristaltic pump 303 is provided in the line 300 in order to deliver blood to the unit 301. An occlusive peristaltic pump 304, in the form shown in Figure 7, is provided and arranged to pump fluid through fluid lines 305, 306 in the direction of respective arrows 307, 308. The line 305 is arranged to deliver fluid from a replacement fluid supply 309 into the blood delivery line 300 so as to dilute the blood in the line 300 prior to it entering the filter unit 301. Fluid line 306 is connected to the filtrate side of the filter unit 301 in order to remove filtrate to a waste vessel 310.

The pump 304, which may simply be thought of as two linked pump m ans (similar to pumps 60, 65, shown in Figure 3), is arranged to pump fluid along fluid lines 305

and 306 at identical rates. As the apparatus provides an occluded system, the volume of fluid removed from the patient by pump 304 along line 306 will be, for substantially all intents and purposes, volumetrically identical to the amount of replacement fluid pumped from supply 309, via line 305, into line 300. Thus, the patient may not suffer a net gain or loss of fluid during haemofiltration. Furthermore, as the rate of pump 304 is controllable, the rate of haemofiltration may be accurately controlled.

A post-dilutional haemofiltration apparatus is shown in Figure 9. The apparatus is similar to that shown in Figure 8. However, in Figure 9, the occlusive pump 304 is arranged to pump fluid in the direction of arrow 307 through a fluid line 320 which delivers replacement fluid into line 302 after the filter unit 301, so as to provide post-dilution. Again, as in Figure 8, the apparatus provides an occlusive system and, accordingly, the volume of fluid removed from the patient by pump 304 along line 306 will be, for all intents and purposes, volumetrically identical to the amount of replacement fluid pumped from supply 309, via line 305, into line 302, the patient thereby suffers no net fluid loss or gain.

It will be appreciated that it may be desired to produce a net loss or gain of patient fluid during haemofiltration. This may be achieved by providing means for affecting the relative rate of fluid flow in line 305, 306 or using an additional pump means, as discussed in relation to the Figure 3 embodiment.

As a predetermined and/or predictable volume of fluid may be removed from or infused into a patient, apparatus may be provided and steps may be taken to control

relatively precisely the blood temperature. For example, a known quantity of fluid at a known temperature may be infused into a patient using the apparatus disclosed herein to either warm up (eg. in the case of a drowning patient) or cool down (eg. in the case of a hyperpyrexial patient) a patient. Thus, the apparatus may include heater means and/or refrigerator means to carry out this task.

The use of slow dialysis (or haemofiltration) made possible by the aforementioned apparatus, may greatly simplify fluid balance management in oliguric patients and may be used to aid temperature control. The apparatus may be of use in treating Adult Respiratory Distress Syndrome by aggressive fluid removal with inotropic support. The arrangement of the apparatus may be such as to allow a means of accurate volumetric control over a prolonged period.

The apparatus disclosed herein may be of utility in any form of dialysis or filtration, for example, in arteriovenous or venovenous filtration or dialysis.

The apparatus disclosed herein may be of particular, although not exclusive, use in the treatment of kidney disorders. Additionally, however, the apparatus may be of use in treating liver disorders. For example, a treatment membrane, preferably a filtration membrane, may be arranged to cooperate with liver fluids and the apparatus may then be used to volumetrically control the fluid and toxins removed from the liver. The ability to provide volumetric control of filtration in relation to liver support may be particularly critical as incorrect fluid balance may lead to swelling in a patient's brain.

The reader's attention is directed to all papers and documents which are filed concurrently with or previous to this specification and which are open to public inspection with this specification, and the contents of all such papers and documents are incorporated herein by reference.

All of the features disclosed in this specification (including any accompanying claims, abstract and drawings), and/or all of the steps of any method or process so disclosed, may be combined in any combination, except combinations where at least some of such features and/or steps are mutually exclusive.

Each feature disclosed in this specification (including any accompanying claims, abstract and drawings), may be replaced by alternative features serving the same, equivalent or similar purpose, unless expressly stated otherwise. Thus, unless expressly stated otherwise, each feature disclosed is one example only of a generic series of equivalent or similar features.

The invention is not restricted to the details of the foregoing embodiment(s). The invention extends to any novel one, or any novel combination, of the features disclosed in this specification (including any accompanying claims, abstract and drawings), or to any novel one, or any novel combination, of the steps of any method or process so disclosed.

CLAIMS

1. Apparatus for treating a patient, a part of which apparatus is arranged to be connected, in use, at or adjacent a treatment membrane having a first side and second side so that body fluid may flow to the first side of the membrane, the apparatus comprising control means for controlling predictably the flow of the fluid across the treatment membrane.

2. Apparatus according to Claim 1, said control means including means for controlling predictably the volume of fluid flowing across the treatment membrane.

3. Apparatus according to Claim 2, wherein said means for controlling the volume of fluid flowing across the treatment membrane is arranged to control predictably the net volume of fluid flowing across the treatment membrane.

4. Apparatus, according to any of the preceding Claims, said control means including means for controlling predictably the net rate of flow of fluid across the treatment membrane.

5. Apparatus according to any of the preceding Claims, the apparatus including an occluded fluid flow line having an occlusive pump means at each end thereof, the fluid flow line being arranged to deliver fluid to the treatment membrane and to remove fluid therefrom.

6. Apparatus according to any of the preceding Claims, including means for measuring the quantity of fluid flowing across the treatment membrane.

7. Apparatus according to any of the previous Claims, first pump means being provided for delivering a fluid to the second side of the membrane and second pump means being provided for removing fluid from said second side.

8. Apparatus according to Claim 7, wherein a fluid flow path between the first and second pump means is totally occluded.

9. Apparatus according to Claim 7 or 8, said first pump means being an occlusive pump.

10. Apparatus according to any of Claims 7 to 9, said second pump means being an occlusive pump.

11. Apparatus according to any of Claims 7 to 10, wherein a link means is provided between said first and second pump means for controlling the relative rates of the respective pumps.

12. Apparatus according to any of Claims 7 to 11, said pump means being arranged to pump fluid in a predetermined fashion.

13. Apparatus according to any of Claims 7 to 12, said first and second pump means being arranged to pump fluid at substantially the same rate.

14. Apparatus according to any of Claims 7 to 13, said first pump means co-operating with a first fluid supply pipe provided between said first pump means and the treatment membrane and said second pump means co-operating with a second fluid supply pipe provided between said second pump means and the treatment membrane, said first

and second fluid supply pipes being of equal cross-sectional area.

15. Apparatus according to any of Claims 7 to 13, said first pump means co-operating with a first fluid supply pipe provided between said first pump means and the treatment membrane and said second pump means co-operating with a second fluid supply pipe provided between said second pump means and the treatment membrane, said first and second fluid supply pipes being of different cross-sectional areas.

16. Apparatus according to any of the preceding Claims, the control means being arranged to deliver fluid to the second side of the treatment membrane and arranged to remove fluid from the second side of the treatment membrane, wherein the rate at which fluid is delivered to the membrane is substantially equivalent to the rate at which fluid is removed from the membrane.

17. Apparatus according to any of the preceding Claims, the control means being arranged to produce a fluid disequilibrium on one side of the treatment membrane and the arrangement being such that fluid is caused to flow across the membrane so as to re-equilibriate.

18. Apparatus according to Claim 17, when appendant to Claim 15, or 16, wherein fluid disequilibrium occurs between said first and second fluid supply pipes.

19. Apparatus according to any of the preceding Claims, wherein, in use, fluid flows between the patient connected on the first side of the treatment membrane and the second part of the treatment membrane in order to re-equilibriate.

20. Apparatus according to any of Claims 8 to 19, the arrangement being such that fluid removal or fluid input into said fluid flow path between said first and second pump means is arranged to cause body fluid to flow respectively from the first side of the treatment membrane to the second side, or from the second side of the treatment membrane to the first side.

21. Apparatus according to any of Claims 7 to 20, a third pump means being provided in said flow path between said first and second pump means.

22. Apparatus according to Claim 21, said third pump means being arranged to remove or input fluid into said fluid flow path between the first and second pump means and control the volume and/or rate of flow of fluid flowing between the first side and the second side of the treatment membrane.

23. Apparatus according to Claim 21 or 22 said third pump means being an occlusive pump.

24. Apparatus according to any of the preceding Claims, fourth pump means being provided and arranged to be connected in a fourth fluid supply path between the patient and the first side of the treatment membrane.

25. Apparatus according to Claim 24, said fourth pump means being an occlusive pump.

26. Apparatus according to any of the preceding Claims, wherein said control means may be arranged to stop an overall net gain of fluid on one side or other of the treatment membrane, the arrangement of the apparatus being such that the rat of flow of fluid from one side of the

membrane to the other side is substantially equal to the rate of flow of fluid from said other side to said one side.

27. Apparatus for treating a body fluid comprising a filter unit comprising a filter membrane having a first side contacted in use by said body fluid and a second side to which components removed from the blood pass, wherein the apparatus comprises means for effecting control of the flow of fluid across the membrane in a pre-determined manner.

28. Apparatus according to Claim 27, wherein the apparatus is arranged and such that the second side of the filter unit may be contacted in use by a dialysis liquid.

29. Apparatus according to Claim 27 or 28, wherein the means for effecting control of the flow of fluid across the membrane in a pre-determined manner comprises means for providing a controlled pressure differential as between a supply line for the dialysis liquid to the second side and a return line therefrom.

30. Apparatus according to any of the features of any of Claims 1 to 26 in combination with any of the features of the apparatus according to any of Claims 25 to 29.

31. A fluid pump comprising a plurality of abutment means rotatably mounted for rotation about an axis, and comprising one or a plurality of abutment surface(s) arranged to cooperate with the abutment means so that, in use, a pipe may be squeezed between an abutment means and an abutment surface, the pump being arranged to pump fluid through at least two pipes, the arrangement being such that, at one instance in use, one pipe may be squeezed at

a first location and another pipe may be squeezed at a second location, the first and second locations being substantially radially disposed of said axis with an angle Θ defined between the radii, wherein Θ is greater than 0°.

32. Apparatus substantially as hereinbefore described with reference to Figures 3 to 8 of the accompanying diagrammatic drawings.

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